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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,884	05/18/2006	Suresh Borsadia	ABL101	8561

39731 7590 04/01/2010

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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
04/01/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/595,884	BORSADIA, SURESH	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,24,25,35 and 45-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14,24,25,35 and 45-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *WO0028989*.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-4, 14, 24, 25, and 45-53 rejected under 35 U.S.C. 102(a,e) as being anticipated by Slugg et al (US 2004/0005358 hereafter '358).

The '358 patent teaches a combination formulation comprising bioactive that treat diabetes and associated disorders [0026]. The combination comprises metformin HCl and a wide variety of active agent included ACE inhibitors, statins, and fibrates such as lovastatin, enalapril, fenofibrate and verapamil [0135-0168, claim 38]. The combination formulation is in the form of coated beads that are loaded in the capsules [0038], liquids suspensions [0040]. The combination can have separate releases for each drug with one drug being an immediate release

and a second drug being prolonged of longer release [Example 5]. Regarding the kit limitation, since the claim does not recite any further structural limitation other kit other than the composition of the drugs, it is the position of the Examiner that the kit limitations have been met by the '358 patent since it fully discloses a combination formulation comprising at least metformin and another active agent such as verapamil. Regarding the specific pharmokinetics of each dosing portion it the position of the Examiner that since these limitation lack any structural elements such as polymer content or disposition, concentrations or ranges, ratios or dosage form, they are merely functional imitations that are met by Example 5. Example 5 teaches a combination formulation comprising an immediate release portion and a prolonged release portion; these disclosures meet the limitations of the claim.

For these reasons the claims are anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-7, 14, 25, 35, and 45-53 rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Slugg et al (US 2004/0005358 hereafter '358) in view of Lewis et al (WO 00/28989 hereafter '989).

As discussed above the '358 patent discloses a combination formulation comprising metformin and a second active agent. The formulation discloses that the combination can comprise a mixture of immediate release and prolonged release portions in the same dosage unit (Example 5). The reference however does not exemplify metformin in this capacity, however it would be obvious to substitute the drug into the prolonged release portion as seen in the '989 patent.

The '989 patent discloses a multilayered tablet comprising metformin and thiazolidinedione (abstract). The thiazolidinedione is pioglitazone present in concentrations from 15-45 mg (col. 4, lin. 5-30, ad page 5, lin. 5-8). The metformin is present in an amount of at least 500 mg (Examples). The layers are formed via conventional tabletting wither the non-biodegradable polymers are mixed with the metformin in a concentration above 35%, specifically 138% of the concentration of the metformin in the layer (page 3, lin. 20-22, Example 4). Metformin is present in a concentration 58% of the total dosage form (Example 4), where pioglitazone can be present in an amount of at least 10%, since 4mg of compound (I) corresponds to at least 10 mg of pioglitazone. The metformin layer comprises inert non-biodegradable includes methacrylic acid copolymers such as Eudragit L and RS powders, along with cellulose derivatives resulting in an extended release profile (col. 3, lin. 6-18). The tablet further comprises diluents, bulking agents such as lactose, and lubricants such as magnesium stearate (pg. 8, lin. 26-36). The tablets are formed using traditional tabletting techniques

(Examples). The polymer can also comprise a mixture of multiple polymers such Eudragit L, Eudragit RS and polyvinylpyrrolidone, present in a ratio of about 1:4.6:0.1 (Example 4). It would have been obvious to substitute the metformin in a prolonged release portion as seen in the '989 patent in order provide prolonged insulin delivery for overnight treatment.

With these things in mind it would have been obvious to combine the prolonged release layer of metformin found in the '989 patent into the combination formulation of the '358 patent in order to provide an immediate insulin drop and a prolonged treatment for overnight treatment. The inclusion of a prolonged metformin portion to a combination therapy is an obvious design choice as seen in the '989 patent and would have resulted in a layered formulation comprising metformin and another drug useful for treating associated diabetes disorders.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 8:00-5:30; every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618
/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618